STATE PROCUREMENT OFFICE

NOTICE OF REQUEST FOR EXEMPTION FROM HRS CHAPTER 103D

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STATE PROCUREMENT OFFICE
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: Health/State Laboratories Division
Name of Requesting Department

Pursuant to HRS § 103D-102(b)(4) and HAR chapter 3-120, the Department requests a procurement exemption for the following:

1. Describe the goods, services or construction:
ARCHITECT HIV Ag/Ab Combo Test and Accessories by Abbott Laboratories

2. Vendor/Contractor/Service Provider:	Abbott Laboratories, Inc.	3. Amount of Request: $ 75,000
4. Term of Contract From: ~~8/15/2013~~ 8/26/13 To: ~~8/14/2014~~ 8/25/14		5. Prior SPO-007, Procurement Exemption (PE): 12-102KBa1

see 9/26/13

6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means:

The State Laboratories' equipment and instrumentation is proprietary to Abbott Laboratories. No other products are USFDA approved to be used with this equipment.
The ARCHITECT HIV Ag/Ab Combo Test by Abbott Laboratories was the first 4th generation assay approved by the USFDA (see S.S. No. 11-059-B) and its use was validated and implemented into our laboratory's HIV testing algorithm. Since the implementation of the ARCHITECT HIV Ag/Ab Combo Test, the Bio-Rad GS HIV Combo Ag/Ab EIA test was USFDA approved for use with plasma/serum on 7/22/2011. Both assays do simultaneous detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2 in human serum or plasma. The ARCHITECT HIV Ag/Ab Combo Assay by Abbott Laboratories uses chemiluminescent microparticle immunoassay (CMIA) technology while the GS HIV Combo Ag/Ab EIA by Bio-Rad uses the older enzyme immunoasssay technology. A reactive result on either assay does not distinguish between the detection of HIV-1 p24 antigen, HIV-1 antibody , or HIV-2 antibody.
Please see the attached page 3.

7. Explain in detail, the process that will be or was utilized in selecting the vendor/contractor/service provider:

The State Laboratories Division uses the 4th generation ARCHITECT HIV Ag/Ab Combo assay to do the initial screening on serum/plasma specimens for the detection of HIV p24 antigen and antibodies to HIV-1 (M and O) and HIV-2 and was validated for use under S.S. No. 11-059B. The SLD equipment and instrumentation is proprietary to Abbott Laboratories. No other products are USFDA approved to be used with this equipment.
Our laboratory currently uses the 3rd generation Genetic Systems HIV-1/2 + O EIA test kits as contingency for screening specimens for HIV-1/2 antibodies in the event the Abbott product is not available although we do not have the capability to detect HIV-1 antigen. Similarly, Bio-Rad's equipment and software is proprietary to Bio-Rad and is not USFDA approved to be used with any other products. Both manufacturer's HIV products are currently being used in our laboratory.

8. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required).
*Point of contact (Place asterisk after name of person to contact for additional information).

Name	Division/Agency	Phone Number	e-mail address
Gail Y. Kunimoto	SLD/MMB	453-6700	gail.kunimoto@doh.hawaii.gov

All requirements/approvals and internal controls for this expenditure is the responsibility of the department. I certify that the information provided above is, to the best of my knowledge, true and correct.

Department Head Signature — Date: 8/23/13

For Chief Procurement Officer Use Only

Date Notice Posted: 8/26/13

Inquiries about this request shall be directed to the contact named in No. 8. Submit written objection to this notice to issue an exempt contract within seven calendar days or as otherwise allowed from date notice posted to:

state.procurement.office@hawaii.gov

Chief Procurement Officer (CPO) Comments:

Approval is granted for the period 08/26/13 to 08/25/14 and is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply (i.e. vendor is required to be compliant on the Hawaii Compliance Express) and award is required to be posted on the Awards Reporting System. Copies of the HCE certificate and awards posting are required to be documented in the procurement/contract file.

If there are any questions, please contact Bonnie Kahakui at 587-4702, or bonnie.a.kahakui@hawaii.gov.

☒ Approved ☐ Disapproved ☐ No Action Required

Chief Procurement Officer Signature — *Date*: 9/3/2013

6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means:

It is not practicable or advantageous for the department to procure by competitive means because our laboratory's HIV testing algorithm uses the ARCHITECT HIV Ag/Ab Combo assay to screen human serum and plasma specimens. Specimens that are initially reactive in the ARCHITECT HIV Ag/Ab Combo assay will be retested in duplicate by the protocol. Repeat reactivity is highly predictive of the presence of HIV-1 p24 antigen and/or HIV-1/HIV-2 antibodies. The assay does not distinguish between the detection of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody. A repeatedly reactive specimen should be investigated further with supplemental confirmatory HIV-specific tests such as western blots or IFA tests, antigen tests, and HIV nucleic acid tests. Supplemental testing of repeatedly reactive specimens obtained from individuals with HIV infection usually confirms the presence of HIV antibodies, HIV antigen, or HIV nucleic acid. A full differential diagnostic work-up for the diagnosis of AIDS and AIDs-related conditions includes an examination of the patient's immune status and a clinical history.

Early after infection with HIV-1, but prior to seroconversion, HIV-1 core antigen may be detected in HIV-1 infected individuals. The ARCHITECT HIV Ag/Ab Combo uses anti-HIV-1 p 24 antibodies as reagents to detect HIV-1 p24 antigen, decreasing the window period and improving early detection of HIV infection. Improving early detection of HIV infection will enable disease control measures to be implemented sooner and identification of patients at risk. In the ARCHITECT HIV Ag/Ab Combo assay the key immunogenic protein for the detection of HIV infections is the viral transmembrane protein (TMP). Antibodies to TMP are consistently among the first to appear during seroconversion of HIV-1 infected individuals and remain relatively strong throughout the asymptomatic and symptomatic stages of infection. The ARCHITECT HIV Ag/Ab Combo detects antibodies to HIV-1 groups M and O, and HIV-2 through the use of five recombinant proteins and two synthetic peptides derived from native TMP sequences of HIV-1 groups M and O, and HIV-2.

Our laboratory currently uses the 3rd generation Bio-Rad HIV-1/2 + O EIA Test Kit as contingency in the event the Abbott product is unavailable (See PE 13-070K) and the Bio-Rad Western Blot Test Kit is used as contingency for the Maxim Biomedical HIV-1 Western Blot Test. The 3rd generation Bio-Rad HIV-1/2 + O EIA Test Kit can also now be used to differentiate between the HIV-1 and HIV-2 antibodies.

It is more advantageous to use the ARCHITECT HIV Ag/Ab Combo by Abbott Laboratories than the GS HIV Combo Ag/Ab EIA because the total running time of the Abbott assay is 30 minutes vs. 2 hours for the Bio-Rad assay. In addition, the Bio-Rad assay is more labor intensive because it is a manual assay vs. the ARCHITECT platform which is an automated system.